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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION	Civil Action No. 17-699(BRM)(LHG) **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS THE FIRST AMENDED CLASS ACTION COMPLAINT (COUNTS 1-5)

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Defendants Novo Nordisk Inc. ("Novo Nordisk") and Sanofi-Aventis U.S. LLC ("Sanofi") ("defendants") respectfully submit this memorandum of law in support of their Motion to Dismiss the First Amended Class Action Complaint (the "complaint" or "FAC") pursuant to Federal Rule of Civil Procedure 12(b)(6).

PRELIMINARY STATEMENT

Through this lawsuit, plaintiffs seek to criminalize a fundamental aspect of the pharmaceutical industry. It is well known—indeed, addressed in federal regulations—that pharmaceutical manufacturers pay rebates to entities called pharmacy benefit managers ("PBMs") to ensure that the manufacturers' prescription medications are made available to consumers. Plaintiffs complain that the prices they paid for insulin were too high because those prices did not reflect the rebates negotiated by the PBMs. Plaintiffs allege that the fact that they did not receive the benefit of rebates that reduced the costs of insulin for other consumers amounts to criminal fraud. But plaintiffs do not allege any facts suggesting that defendants deceived plaintiffs about the prices that plaintiffs paid for insulin. Nor do they allege that defendants promised plaintiffs that insurers and PBMs would pass along to them the benefit of any rebates. Indeed, nowhere in their 204-page complaint do plaintiffs identify any fraudulent, unfair, or unconscionable conduct by defendants. No law dictates that all consumers must receive the most favorable pricing provided to any other purchaser, either for prescription medications or for

any other product. Nor is there any legal requirement for a manufacturer to disclose to consumers or the public the net amount it receives for its products, or for a manufacturer to provide rebates to any consumers.

Commercial and government-run health insurers hire PBMs to manage their prescription drug costs. In fact, the three largest PBMs together govern access to prescription medication for approximately 180 million people. Because of the purchasing power they wield, the PBMs are able to extract rebates from prescription drug manufacturers.[1] As plaintiffs allege, the PBMs demand rebates from the manufacturers in exchange for placing manufacturers' products on insurance formularies. These formulary decisions usually determine which insulin an insured individual will use.

It is widely known that manufacturers pay rebates to PBMs so that patients (in consultation with their doctors) can choose the manufacturers' products—indeed, defendants publicly disclose that they pay these rebates. And in

[1] Before making the strategic decision to toll their claims against the PBMs, some plaintiffs alleged that the PBMs named as defendants in their complaints—CVS Health, Express Scripts, and OptumRx—are "engaging in extortion" by extracting rebates from manufacturers. *See Boss, et al. v. CVS Health Corp., et al.*, Case No. 2:17-cv-01823 (D.N.J. Mar. 17, 2017), Dkt. No. 1 ¶ 25; *see also Christensen, et al. v. Novo Nordisk Inc., et al.*, Case No. 3:17-cv-02678 (D.N.J. Apr. 20, 2017), Dkt. No. 1 ¶ 10 ("The contest rigged up by the PBMs creates the incentive and framework for the Drug Manufacturers to raise their insulin list prices.").

competitive marketplaces, it is entirely rational—and lawful—for manufacturers to discount their products (through the payment of rebates) in exchange for having their products appear on the formularies that insurers utilize to make coverage decisions for the vast majority of patients who use the manufacturers' medications.

Although discounting is a common and permissible feature of many competitive industries, plaintiffs try to portray what they characterize as the "benchmark price" for insulin as fraudulent because it does not reflect "the [rebates] the drug manufacturers offer PBMs." FAC ¶ 11. That is wrong on many levels. Manufacturers are not required to set their prices at a level that accounts for rebates offered to other market participants, such as PBMs. And plaintiffs do not allege that defendants ever represented that their "benchmark" prices reflect the rebates paid to PBMs. In fact, federal law makes clear that the list prices do not reflect any rebates: "the manufacturer's list price for the drug"—also known as the "wholesale acquisition cost"—is defined as "*not including* prompt pay or other *discounts, rebates or reductions in price*." 42 U.S.C. § 1395w-3a(c)(6)(B) (2012) (emphasis added). The mere existence of a difference—or, in plaintiffs' terminology, a "spread"—between defendants' "benchmark" prices and the amount defendants receive after paying PBM rebates simply does not amount to fraud.

Defendants acknowledge that pharmaceutical pricing is an important issue, especially given how recent trends in the design of insurance benefits have affected certain patients' out-of-pocket costs. But as plaintiffs recognize, manufacturer rebates to PBMs are not unique to sales of insulin. The entire branded pharmaceutical industry functions in the same way. As a result, the relief plaintiffs seek in this litigation would not only require this Court to regulate the pricing of insulin, but also would impact the entire pharmaceutical industry at large. Plaintiffs have not provided any factual or legal basis for that extreme request. While the pricing system may benefit from reforms, this issue is not properly addressed via *in terrorem* claims seeking treble-damages under the federal racketeering statute or via conclusory invocations of every state's consumer-protection laws.

As demonstrated below, the Court should dismiss plaintiffs' RICO and New Jersey Consumer Fraud Act ("NJCFA") claims (i.e., Counts 1 through 5). The Court should also dismiss plaintiffs' myriad other state law claims (i.e., Counts 6 through 59).[2] Moreover, given that plaintiffs have now collectively filed no fewer

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[2] In a separate brief contemporaneously filed with this one, defendants explain why plaintiffs' state law claims (in addition to plaintiffs' NJCFA claims) all fail. *See* Defendants' Memorandum of Law in Support of Motion to Dismiss the First Amended Class Action Complaint (Counts 6-59) ("State Law Brief"). Because plaintiffs fail to plead facts showing that defendants did anything
(….continued)

than *seven* complaints against defendants—without ever articulating a coherent and plausible theory of liability—the dismissal should be with prejudice.

ALLEGATIONS[3]

A. The Parties

Defendants are pharmaceutical companies headquartered in the United States. *See* FAC ¶¶ 157-158. Defendants research, develop, and manufacture prescription medications, including insulins. *See id*. Defendants have been at the cutting edge of innovation in insulin treatments for decades, and consistently have

(continued….)

fraudulent, unfair, or unconscionable—as demonstrated in this brief—all of their state law claims necessarily fail as well. In addition to that fundamental flaw, the State Law Brief explains a number of other defects in the state law claims.

[3] These allegations are assumed to be true solely for purposes of defendants' motion to dismiss. In considering a motion to dismiss, the Court may consider the materials referenced and incorporated into the complaint and matters of public record. *See*, *e.g.*, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 568 n.13 (2007) ("the District Court was entitled to take notice of the full contents of the published articles referenced in the complaint"); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 166 (3d Cir. 2014) (citation omitted); *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 623 (D.N.J. 2002) (on a motion to dismiss, a court may consider matters of public record and "may properly refer to the full text" of documents cited in the complaint).

Tellingly, after defendants demonstrated, in their motion to dismiss the prior iteration of plaintiffs' complaint, that a number of sources incorporated into that complaint actually support defendants' position —including publications of the Congressional Budget Office, the U.S. Department of Health and Human Services, and the Kaiser Family Foundation—plaintiffs scrubbed references to those sources from their FAC.

brought to market in the United States new insulin products representing "innovation." *See id.* ¶¶ 224-228.

The insulins at issue in this case are "analog" insulins, which are synthetic insulin products created by modifying the molecular structure of natural insulin created by the human body. *See id.* ¶ 226. Defendants' analog insulins are widely viewed as the best-in-class treatments for insulin-dependent diabetics, based on their ability to "more closely mimic the way the human body naturally absorbs insulin released by the pancreas." *Id.* ¶¶ 229-233.

Plaintiffs are sixty-six identified individuals (and one Jane Doe) with diabetes, or with relatives who have diabetes, who allege that they have used various analog insulins produced by defendants and have made out-of-pocket payments based on a "benchmark price." *Id.* ¶¶ 21-156.[4] Plaintiffs define the "benchmark price" as the "Average Wholesale Price (AWP) or the mathematically-related, Wholesale Acquisition [Cost] (WAC)." *Id.* ¶ 174. Plaintiffs bring this action on behalf of a putative class of "[a]ll individual persons in the United States . . . who paid any portion of the purchase price for a prescription of Lantus, Levemir, Novolog, Apidra, and/or Toujeo at a price

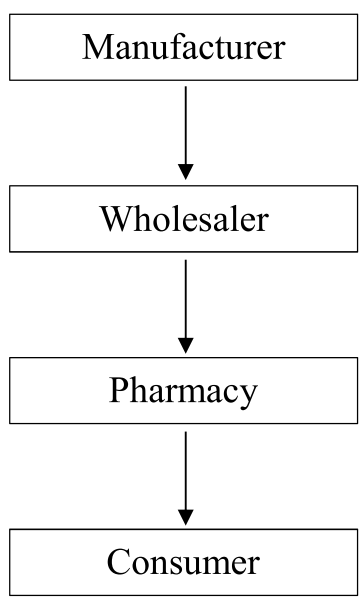
[4] Two plaintiffs allege that they currently use prior-generation insulins known as "human insulins." *See* FAC ¶¶ 140, 142. Human insulins sell for a fraction of the cost of analog insulins and are safe alternatives for many consumers. *See id.* ¶¶ 228 tab. 2, 232.

calculated by reference to a benchmark price . . . for purposes other than resale." *Id.* ¶ 282.

B. The Distribution of, and Payment <u>For, Branded Prescription Drugs</u>

The physical distribution of a branded prescription drug such as analog insulin involves three discrete transactions. *First*, a drug manufacturer sells its medication to a wholesaler. *Id.* ¶¶ 163-164. *Second*, the wholesaler takes possession of the medication and re-sells it to a pharmacy. *Id.* ¶¶ 164, 170 fig. 3. *Third*, the pharmacy sells the medication to consumers. *Id.* ¶¶ 166-167, 170 fig. 3.

Figure 1
<u>The Physical Path of a Prescription Drug</u>



Health insurers and PBMs, which many insurers hire to manage their prescription drug benefits, are not directly involved in this distribution chain because they do not take physical possession of the medication. *Id.* ¶¶ 165-166.

Three separate payments are associated with these transactions: (1) from the wholesaler to the manufacturer; (2) from the pharmacy to the wholesaler; and (3) from the consumer—and her insurer, if any—to the pharmacy. *Id.* ¶ 168. In addition to these transactions, there frequently is an additional payment of a rebate from the manufacturer to the insurer or the insurer's PBM. *Id.* ¶ 169. The nature of these payments, and the manner in which they are determined, are described below.

Payments from Wholesalers to Manufacturers Based on Benchmark Prices. Wholesalers pay manufacturers based on the publicly reported list price established by the manufacturer, which is known as the Wholesale Acquisition Cost ("WAC"). *Id.* ¶ 176. WAC is defined by federal statute. It is "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . ." 42 U.S.C. § 1395w-3a(c)(6)(B) (2012).

Consistent with the statutory definition, wholesalers pay the manufacturer WAC minus small percentage discounts that they can earn for prompt payment and meeting other incentives. *See* FAC ¶¶ 169, 176, 181; *Nat'l Ass'n of Chain Drug Stores v. New England Carpenters Health Benefits Fund*, 582 F.3d 30, 36 (1st Cir. 2009). Manufacturers report the WAC for their drugs to third-party publishers,

which publish the WAC in publicly available drug-pricing compendia.[5] Plaintiffs refer to WAC as a "benchmark price" or the "sticker price."[6]

***Payments from Pharmacies to Wholesalers Based on Benchmark Prices*.** Wholesalers sell to pharmacies at a price they negotiate with each pharmacy. FAC ¶ 170 & fig. 3. In practice, wholesalers are able to negotiate a small percentage markup over what they paid to the manufacturer. *See Chain Drug Stores*, 582 F.3d at 36. Because wholesalers pay manufacturers WAC minus a small percentage discount and then add a small percentage markup when reselling to pharmacies, the prices paid by pharmacies are frequently very close to WAC. *See id.*; *see also* FAC ¶ 181; 42 U.S.C. § 1395w-3a(c)(6)(B) (2012). The average prices paid by pharmacies are publicly available: The federal government publishes the average price for most prescription drugs on the internet on a weekly basis.[7]

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[5] In addition, manufacturers are required to report to the federal government the average price that wholesalers pay for each drug after accounting for any discounts earned by the wholesalers, which is called Average Manufacturer Price ("AMP"). 42 U.S.C. §§ 1396r-8(b)(3)(A), 1396r-8(k)(1) (2012).

[6] Plaintiffs also use the terms "sticker price" and "benchmark price" to refer to AWP, which is mathematically related to WAC. *See* FAC ¶¶ 1, 2, 174.

[7] *See Pharmacy Pricing*, Medicaid.gov, www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html (last visited May 9, 2018) (linking to downloadable files providing weekly National Average Drug Acquisition Cost data on a per unit basis for drugs classified by a National Drug Code). The Court can take judicial notice that this pricing information is publicly available. *See, e.g.*, *Vanderklok v. United States*, 868 F.3d
(….continued)

Payments from Consumers and Their Insurers to Pharmacies Based on Negotiated Prices. Drug manufacturers such as defendants do not sell drugs directly to consumers, and do not set the price that a consumer pays for a prescription medication. FAC ¶¶ 163, 171. Rather, the consumer's payment is determined by her pharmacy and, for insured consumers, by the terms of her insurance. *Id.* ¶¶ 181, 183-184.

If a consumer is *uninsured*, then the pharmacy unilaterally determines the price the consumer must pay; different pharmacies can charge different prices for the same medication. *See id.* ¶¶ 11 n.1, 182, 285. If a consumer is *insured*, the insurer or its PBM negotiates the price with the pharmacy. *See id.* ¶¶ 166, 170 fig. 3, 171.[8] The insurer and the consumer each pay a portion of this negotiated price, with the consumer's share determined by the terms of her insurance coverage—namely, the deductible and copayment or coinsurance requirements. *Id.* ¶¶ 165, 183-184. A "copayment" refers to a fixed dollar amount per prescription paid by

(continued….)

189, 205 n.16 (3d Cir. 2017) (taking judicial notice of "information [that] is publicly available on government websites").

[8] *See also* 42 C.F.R. §§ 423.104(d), (e), (f)(1), (g)(1) (2015) (requiring Medicare Part D plans to provide beneficiaries with "access to negotiated prices"); *id.* § 423.100 (defining "negotiated price"); 42 U.S.C. § 1395w-114a(g)(6) (2012) (defining "negotiated price" for purposes of the Medicare coverage gap discount program). PBMs form pharmacy networks, and use their leverage to negotiate with pharmacies for discounted prices in exchange for access to their networks.

the consumer, and "coinsurance" refers to a consumer's payment of a specified percentage of the negotiated price. *Id.* ¶¶ 193-194. Plaintiffs allege that prior to meeting her deductible, a consumer pays the pharmacy the full negotiated price, with no contribution from the insurer. *See id.* ¶ 184. After a consumer satisfies her deductible, she pays only the copayment or coinsurance, and the insurer pays the remainder of the negotiated price. *Id.* ¶¶ 195, 200-201.

Plaintiffs allege that the prices charged by pharmacies to uninsured consumers and the prices set by insurers and PBMs for consumers subject to deductible and coinsurance requirements are related to the "benchmark" or "sticker" price.[9] *Id*. ¶¶ 2, 209. Plaintiffs seek to represent a putative class covering these consumers. *Id*. ¶¶ 282-286.

"Net Prices" After Rebate Payments from Manufacturers to PBMs. PBMs are retained by health insurers to manage their prescription drug benefits and negotiate with drug companies and pharmacies on their behalf. FAC ¶ 166. "Competition among PBMs for the business of [health insurers] is fierce." *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 244 F.R.D. 79, 82 (D. Mass. 2007).

[9] This includes coinsurance payments by consumers in Medicare Part D's so-called "donut hole." FAC ¶¶ 199-200.

PBMs do not purchase prescription drugs or make any payments to manufacturers. FAC ¶ 166. Rather, acting on behalf of insurers, PBMs negotiate discounts—in the form of rebates—from manufacturers. *Id.* ¶¶ 4, 169, 170 fig. 3. Plaintiffs allege that PBMs "take a cut" of these rebates "with the rest passed on to their health insurer clients." *See id.* ¶ 204; *see also id.* at ¶¶ 4, 201. These rebates "effectively lower the cost paid for the product by the plan sponsor" and "lower the sponsor's cost of providing the benefit." *J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 2005 WL 1396940, at *9 (S.D. Ohio June 13, 2005); *see also In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 434 (3d Cir. 2009) ("Efficiencies and cost savings are achieved by PBMs in a variety of ways, including negotiating discounts or rebates from drug manufacturers, providing mail order prescription service to plan members, [and] contracting with retail pharmacies for reimbursement when prescriptions are filled for plan members."). According to plaintiffs, however, some insurers have elected not to pass on manufacturer rebates to consumers who pay for prescription drugs during the deductible or coinsurance periods of their health insurance plans. *See, e.g.*, FAC ¶ 200. Whether and how the insurer passes through the rebate to these consumers depends on the terms of the consumer's insurance policy. *Id.* ¶¶ 200-201.

Plaintiffs contend that the "benchmark prices" that defendants have charged for their insulin products are "fraudulent" because they do not account for

manufacturer rebate payments to PBMs. See *id.* ¶¶ 252, 255. According to plaintiffs, "[t]he price reductions the drug manufacturers offer PBMs are not reflected in the price tags the consumers see." *Id.* ¶ 11. That allegation, however, conflates two unrelated sets of transactions involving different entities. The "benchmark prices" (WAC and AWP) relate to the actual prices paid by wholesalers and pharmacies to acquire a drug. Separately, manufacturers pay rebates to PBMs—who negotiate for them on behalf of insurers—to help secure favorable formulary placement. *Id.* ¶ 4. The rebate to the *PBM*—which typically does not take possession of any drugs (*id.* ¶ 166)[10]—does not reduce or offset the amounts that the *wholesaler and pharmacy* already have paid.

Plaintiffs go on to define "net price" as the "prices institutional payers pay," and allege a fraudulent scheme based on the "spread" between that price and the "benchmark price." *See, e.g.*, *id.* ¶¶ 202, 206. But unlike the "benchmark price," the so-called "net price" is not charged or paid by anyone. *See id.* ¶ 170 fig. 3. Nor do manufacturers "offer[]" their net price to PBMs. *Id.* ¶ 2. Instead, the "net price" simply refers to what the drug manufacturer *realizes in revenue* after subtracting the amount of the rebates that it negotiates and pays to PBMs. *See id.*

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[10] In an exception, PBMs that operate mail-order pharmacies purchase drugs from wholesalers solely in their capacity as sellers to consumers. *See* FAC ¶¶ 7, 166.

¶¶ 169, 170 fig. 3. The "net price" realized by the manufacturer is not a single price—it instead depends on a particular PBM's ability to negotiate rebates. *See id.* ¶ 171.

A simple example based on the complaint illustrates this point. *See id.* ¶ 201. Imagine that, based on the benchmark price set by the manufacturer, the wholesaler pays $367.50 to the manufacturer for analog insulin and the pharmacy then pays $375.00 to the wholesaler. Assume further that the PBM has negotiated a price of $382.50 with the pharmacy. The pharmacy collects a $30.00 copayment from the consumer and $352.50 from the PBM (on the insurer's behalf). Pursuant to a separately negotiated agreement with the particular PBM, the manufacturer later pays a $150.00 rebate to the PBM. The rebate reduces the manufacturer's "net price" to $217.50 ($367.50 – $150.00) and the PBM's net cost to $202.50 ($352.50 – $150.00), but it does not change the prices paid by the wholesaler ($367.50) and pharmacy ($375.00).

C. Manufacturer-PBM Rebate Negotiations

Plaintiffs assert that PBM rebates are part of a scheme to inflate the price of analog insulin but, contrary to plaintiffs' rhetoric, their specific allegations show that the rebates are simply price discounts negotiated with drug companies. *See, e.g.*, *id.* ¶¶ 169, 180.

According to plaintiffs, the three largest PBMs (CVS Health, Express Scripts, and OptumRx) collectively "cover over 80% of the insured market: in total, 180 million lives," and have "great[] leverage to negotiate" with manufacturers. *Id.* ¶¶ 4, 205. Armed with this leverage, the PBMs create formularies—ranked lists of drugs. *Id.* ¶ 180. Plaintiffs allege that "[h]ealth insurers cover all or a portion of their members' drug costs based on whether and where drugs fall on their PBMs' formularies." *Id.* If a drug is excluded from these formularies or placed in a less-favored reimbursement tier on the formulary, consumers may be required to pay the full cost of the medication or a larger share of the cost (through higher copayments or coinsurance percentages). *Id.* ¶¶ 193-194. That, in turn, will reduce demand for, and use of, the drug. *Id.* ¶¶ 5, 241. The use of formularies, according to plaintiffs, thus gives the PBMs enormous power to extract rebates from manufacturers. *Id.* ¶ 241 ("PBMs control the formularies that determine whether people living with diabetes will purchase Novo Nordisk or Sanofi's analog insulins.").

The "PBMs have the greatest leverage" to negotiate rebates from drug manufacturers in the case of analog insulin. *Id.* ¶ 205. Analog insulins are "in the same therapeutic class and are perceived to have similar effectiveness and risk profile." *Id.* Plaintiffs allege that as a result, Novo Nordisk and Sanofi

aggressively compete against each other by offering rebates to PBMs for formulary placement. *Id.* ¶ 241.[11]

D. <u>The Alleged "Scheme"</u>

Plaintiffs have alleged a pricing "scheme" to "widen a secret spread between the manufacturers' published and misleading benchmark prices, and their undisclosed, net selling prices for their analog insulins." *Id.* ¶ 2. According to plaintiffs, "PBM profits are tied to the size of the spread between the benchmark price and actual net selling prices." *Id.* ¶¶ 2, 210. Thus, manufacturers such as defendants allegedly have an "incentive" to offer a larger spread to PBMs than those offered by their competitors because they "'don't want their products disadvantaged.'" *Id.* ¶ 207.

The allegedly fraudulent pricing "scheme" is based on two theories. First, plaintiffs claim that defendants "publicly report one price—the benchmark or 'sticker' price—for their analog insulins while secretly offering a far lower price—the net price—to the largest PBMs." *Id.* ¶ 2. But the benchmark price is not merely something that defendants "report." Defendants actually charge their

[11] *See also* Allison Tsai, *The Rising Cost of Insulin* at 2, Diabetes Forecast (Mar. 2016) (manufacturers "offer [PBMs] big discounts" to "better position their drug against competitors—so their drug ends up on a lower tier while their competitor's is on a higher tier with higher copays") (incorporated by reference by FAC ¶ 170 n.5).

wholesaler customers the benchmark price (WAC) for analog insulin, minus small incentive discounts (such as for prompt payment).

In any event, plaintiffs do not allege that it is unlawful for drug manufacturers to raise list prices, as do other manufacturers throughout the economy. Nor do plaintiffs make any attempt to explain why it is fraudulent to offer rebates to the PBMs, who drive high-volume purchasing, simply because the PBMs may not fully pass through the rebates to consumers at the point of sale. To the contrary, plaintiffs concede that the payment of rebates is not inherently wrongful. *Id.* ¶ 6.[12] Indeed, plaintiffs claim that the "legitimate use of discounts and rebates" is "not at issue in this case." *Id.*

Plaintiffs contend, however, that because PBMs allegedly do not "negotiate discounts or rebates that lower the manufacturers' net selling prices" and instead "pad [their] pockets" with such rebates, the rebates that are the subject of this lawsuit are not legitimate. *Id.* ¶¶ 2, 6. But plaintiffs nowhere allege that PBMs pass along rebates for analog insulin to their clients any differently than they pass along rebates for other brand name drugs. Further, as the federal government has

[12] Plaintiffs admit that, by securing preferred formulary placement, a manufacturer's payment of rebates lowers the coinsurance or copayment that a consumer must pay for its medicines. FAC ¶¶ 193-194. In doing so, plaintiffs concede that most consumers—those that are insured—*do* benefit from the payment of rebates. These same consumers also benefit indirectly from rebates through lower insurance premiums.

recognized, there is nothing unique about list price increases coupled with rebate payment increases. 82 Fed. Reg. 56,336, 56,419 (Nov. 28, 2017) ("[M]anufacturer rebates have grown dramatically relative to total Part D gross drug costs each year since 2010."). Federal and state governments have long relied on rebate payments to reduce their own expenditures on branded drugs.[13] In fact, the Federal Trade Commission ("FTC") has openly criticized legislative proposals to require public disclosure of manufacturer rebates. As the FTC concluded, the required disclosure of aggregate rebates paid to the PBMs would increase the risk that manufacturers would not compete aggressively through rebates, and "may lead to higher prices for PBM services and pharmaceuticals."[14]

Second, plaintiffs allege that defendants represented that the benchmark prices were "reasonable approximations of the insulins' real prices." FAC ¶¶ 3, 12-13, 254, 302, 350. But plaintiffs do not identify a single such statement in their

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[13] *See, e.g.*, 42 U.S.C. § 1396r-8(a) (2016) (requiring manufacturers, since the 1990s, to pay rebates to the Medicaid program as a condition of providing insurance coverage for the manufacturer's medications); Patient Protection and Affordable Care Act, Pub. L. 111-148, § 2501(c), 124 Stat. 119 (2010) (substantially increasing the amount of Medicaid rebates that manufacturers must pay); *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 649 (2003) (describing how states negotiate "supplemental" Medicaid rebate agreements with manufacturers).

[14] Susan A. Creighton, *et al.*, Federal Trade Commission, Letter to Assembly Member Greg Agharzarian, at 4, 9 (Sept. 7, 2004), *available at* https://goo.gl/z8R6j5.

204-page complaint—indeed, they do not even identify a single representation that would lead a consumer to believe that the price the consumer paid for analog insulin is similar to the benchmark price.

Plaintiffs' allegations of fraud boil down to the contention that the price they paid for insulin at the pharmacy should have been directly and fully offset by the rebates that the defendant manufacturers paid to PBMs. *See, e.g.*, *id.* ¶ 11 ("The price reductions the drug manufactures offer PBMs *are not reflected in the price tags the consumers see*) (emphasis supplied); *id.* ¶ 262 ("plaintiffs and members of the class have overpaid for their analog insulins").[15] Defendants have no control, however, over whether or how a PBM or health insurer passes through the rebate to the insured consumers. *See id.* ¶ 204. Recognizing that fact, the federal government has identified the issue of rising list prices and rebates as one to be fixed by insurers, not manufacturers. 82 Fed. Reg. 56,336, 56,419.

Plaintiffs nevertheless allege that Novo Nordisk and Sanofi each formed a distinct "association-in-fact" enterprise with each of the three largest PBMs. *Id.* ¶ 300. Each "enterprise" allegedly engaged in "a fraudulent scheme" to "exchang[e]

[15] This is actually a generous interpretation of plaintiffs' position. Plaintiffs apparently believe not only that insured consumers should have received rebated amounts at the point of sale, but that uninsured consumers—who by definition do not have health insurers and PBMs negotiating on their behalf, and whose purchases thus do not trigger the payment of rebates—should have received lower point-of-sale pricing too.

kickbacks . . . for preferred formulary positions" for a defendant's insulin products. *Id.* ¶ 312. Plaintiffs argue that each of the alleged schemes entails a "pattern" of predicate acts of federal mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1343. *See id.* ¶ 326. Plaintiffs allege in conclusory fashion that the asserted RICO violations "have directly and proximately caused the plaintiffs and members of the class to be injured" through "inflated payments based on fictitious benchmark prices for the analog insulins." *Id.* ¶ 336; *see also id.* ¶¶ 20, 266, 341, 354.

LEGAL STANDARDS

A. Rule 8(a)

A complaint should be dismissed if, assuming its well-pleaded allegations of fact are true, it fails to plausibly show that the plaintiff is entitled to relief. *See, e.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). Legal conclusions, "labels," and other conclusory allegations—such as "unadorned, the defendant-unlawfully-harmed-me accusation[s]"—are not assumed to be true and cannot establish entitlement to relief. *Id.* at 678. Rather, a plaintiff must allege "sufficient factual matter" that, taken as true, allows the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*; *see also Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (courts "are not compelled to accept unsupported conclusions and unwarranted inferences, or a legal conclusion couched as a factual allegation" (quotations omitted)).

B. **Rule 9(b)**

In addition, claims sounding in fraud must be pleaded with the particularity required by Rule 9(b), including identification of "specific fraudulent statements, omissions, or misrepresentations." *Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 85-86 (3d Cir. 2015). The allegations must be specific enough not only to put "defendants on notice of the precise misconduct with which they are charged," but also—and more importantly—"to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Lum v. Bank of Am.*, 361 F.3d 217, 223-24 (3d Cir. 2004), *abrogated on other grounds as recognized by In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 323 n.22 (3d Cir. 2010).

C. **RICO Claims**

Congress enacted RICO as part of the Organized Crime Control Act of 1970 "for the purpose of seek[ing] the eradication of organized crime in the United States." *Beck v. Prupis*, 529 U.S. 494, 496 (2000) (internal quotation marks and citation omitted). RICO targets criminal activity, including conduct that is "indictable" as federal mail or wire fraud. 18 U.S.C. § 1961(1)(B) (2012) (citing federal criminal statutes including 18 U.S.C. §§ 1341 & 1343); *see, e.g.*, *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 647 (2008). Thus, a prerequisite for any civil liability under RICO claims premised on mail and wire fraud, like plaintiffs' claims, is that the defendants engaged in deceptive conduct *with the*

specific intent to defraud. *See, e.g.*, *Advanced Oral Techs., L.L.C. v. Nutres Research, Inc.*, 2011 WL 198029, at *8 (D.N.J. Jan. 20, 2011).

"[A]ll too frequently," however, civil RICO plaintiffs "attempt to mold their claims to the RICO form even though their injuries do not fall within those intended to be addressed by the [statute]." *Rosenson v. Mordowitz*, 2012 WL 3631308, at *4 (S.D.N.Y. Aug. 23, 2012). "'[E]xperience reveals that many plaintiffs, rather than fostering RICO's mission as private attorneys general aiding public law enforcement, actually appear as private prospectors digging for RICO's elusive gold, and more often than not generating substantial costs rather than net gains to the public.'" *Id.* (quoting *Gross v. Waywell*, 628 F. Supp. 2d 475, 481 (S.D.N.Y. 2009)). Complaints that successfully plead a bona fide claim under RICO are "rare." *Id.* at *5; *see also Gross*, 628 F. Supp. 2d at 479-80, 495 ("the incidence of favorable judgments for RICO plaintiffs is . . . stunningly awful" (internal quotation marks omitted)).

This backdrop makes clear why civil RICO claims are among the most difficult claims to plead. *See, e.g.*, *Rogers v. Morrice*, 2013 WL 1750004, at *6 (D.N.J. Apr. 23, 2013) ("fraud and civil RICO claims are subject to demanding pleading standards"). "Because the mere assertion of a RICO claim . . . has an almost inevitable stigmatizing effect on those named as defendants, . . . courts should strive to flush out frivolous RICO allegations at an early stage of the

litigation." *Grant v. Turner*, 2010 WL 4004719, at *3 (D.N.J. Oct. 12, 2010); *see also Katzman v. Victoria's Secret Catalogue*, 167 F.R.D. 649, 655 (S.D.N.Y. 1996) ("Civil RICO is an unusually potent weapon—the litigation equivalent of a thermonuclear device." (citation omitted)), *aff'd*, 113 F.3d 1229 (2d Cir. 1997). This is especially true of RICO claims premised on mail or wire fraud, which "must be particularly scrutinized because of the relative ease with which a plaintiff may mold a RICO pattern from allegations that, upon closer scrutiny, do not support it." *Kolar v. Preferred Real Estate Invs., Inc.*, 361 F. App'x 354, 363 (3d Cir. 2010) (quotation omitted). "Specificity is imperative" in pleading RICO claims because "of the heavy penalties imposed upon an unsuccessful RICO defendant." *Va. Surety Co., Inc. v. Macedo*, 2010 WL 3429530, at *7 (D.N.J. Aug. 27, 2010).

To state a civil RICO claim, plaintiffs must plead particularized facts that plausibly show (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity. *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985). In addition, plaintiffs must allege that they have suffered a cognizable injury to their business or property, and that their injury was caused "by reason of" a violation of RICO. 18 U.S.C. § 1964(c) (2012); *see, e.g.*, *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 246 (3d Cir. 2012). The RICO violation must be *both* a "but-for" *and* a proximate cause of the plaintiff's

injury. *See Bridge*, 553 U.S. at 654. To plead proximate causation, a complaint must demonstrate a "'direct relation between the injury asserted and the injurious conduct alleged.'" *Id.* (quoting *Holmes v. Secs. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992)).

D. NJCFA Claims

To state a claim under the NJCFA, a plaintiff must show (1) unlawful conduct by the defendant, (2) an "ascertainable loss" by the plaintiff, and (3) a causal relationship between the unlawful conduct and the ascertainable loss. *See DeGennaro v. Am. Bankers Ins. Co. of Fla.*, 2017 WL 2693881, at *6 (D.N.J. June 22, 2017) (Martinotti, J.). Where, as here, plaintiffs' allegations sound in fraud, claims under the NJCFA are subject to Rule 9(b)'s heightened pleading standard. *Id.* at *5.

ARGUMENT

As set forth in greater detail below, plaintiffs' RICO claims fail for a number of reasons.

First, plaintiffs lack statutory standing to assert any RICO claims because they are "indirect purchasers" who do not purchase analog insulin directly from any defendant. This indisputable fact alone disposes of plaintiffs' RICO claims.

Second, even if plaintiffs had standing, they have not alleged the most basic element of a RICO claim: the existence of a predicate act. Plaintiffs assert

violations of the criminal mail and wire fraud statutes, but the complaint does not allege a single instance in which a defendant misrepresented the nature of its benchmark prices or withheld information that it had a duty to disclose—much less that any defendant specifically intended to defraud consumers (or anyone else). The mere fact that some consumers pay a relatively higher price for insulin because they are uninsured or have a less favorable insurance policy than other consumers—and therefore do not receive the benefit of rebates paid to PBMs—cannot plausibly support a claim of criminal fraud.

Third, plaintiffs fail to allege that each defendant shared a "common purpose" (an essential element of a RICO enterprise) with the PBMs, and similarly fail to allege that the defendants operated or managed the affairs of the alleged enterprises, as opposed to defendants' own affairs.

Fourth, plaintiffs fail to plead that any purported misrepresentation or omission proximately caused *any* injury to plaintiffs. Even if defendants had fully disclosed the "net price" they realized after paying rebates to PBMs, it would not have changed the amounts that plaintiffs paid for insulin. The payments made by plaintiffs are dictated by pharmacies and their own insurers, not by defendants.

Fifth, plaintiffs' RICO conspiracy claim fails as well, both because plaintiffs have not plausibly alleged a substantive RICO violation and because plaintiffs have not plausibly alleged any agreement between defendants to violate RICO.

The NJCFA claims fail for similar reasons. Plaintiffs cannot state a NJCFA claim because they do not allege with the required specificity how defendants violated the statute, when and where any purported misrepresentations were made, or who made any such statements. Plaintiffs also fail to allege that they suffered the "ascertainable loss" necessary to state a NJCFA claim. Lastly, although plaintiffs claim that defendants' scheme "inflated" the price of insulin, courts have rejected attempts to rely on a price inflation theory to establish a claim under the NJCFA.

I. The RICO Claims Should Be Dismissed

A. Plaintiffs' Claims Are Barred by the Indirect Purchaser Rule

Plaintiffs lack RICO standing because they are not the first party in the distribution chain who pay for insulin based on the "benchmark" price. Plaintiffs' core allegation is that defendants each engaged in a "scheme" to "publicly and artificially inflat[e] the benchmark prices of their analog insulin." FAC ¶ 20. Plaintiffs acknowledge, however, that consumers are not the first party (or even the second) to pay for analog insulin based on the purportedly inflated benchmark price. Instead, defendants' analog insulins are sold to wholesalers at prices "based on the benchmark prices that are set by manufacturers," which in turn sell them to pharmacies, hospitals, and clinics at prices that approximate the benchmark prices. *See id.* ¶¶ 164, 176; 42 U.S.C. § 1395w-3a(c)(6)(B) (2012) ("The term 'wholesale

acquisition cost' means, with respect to a drug . . . , the manufacturer's list price for the drug . . . to wholesalers or direct purchasers. . . .").[16] Because plaintiffs are three levels down the distribution chain from defendants, they are classic "indirect purchasers" who lack standing under RICO. *See McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 848, 855 (3d Cir. 1996) ("only the purchaser immediately downstream" has standing to assert RICO claims for payment of "excessive prices").

The indirect purchaser rule originated in the antitrust context. In *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) and *Kansas v. UtiliCorp United Inc.*, 497 U.S. 199 (1998), the Supreme Court established a bright-line rule that *only* the immediate purchaser has standing to sue a manufacturer for violations of federal antitrust laws. Any other approach would pose "the risk of duplicative recovery and the potential for overly-complex damages and apportionment calculations." *McCarthy*, 80 F.3d at 851 n.14. Because RICO's private cause of action, 18 U.S.C. § 1964(c), was modeled on the Clayton Act, "antitrust standing principles apply equally to allegations of RICO violations." *Id.* at 855. Accordingly, the Third Circuit has held that the "precepts taught by *Illinois Brick* and *Utilicorp*

[16] *See also* FAC ¶ 174 (explaining that "a drug's benchmark price" refers to "its Average Wholesale Price (AWP) or the mathematically-related, Wholesale Acquisition [Cost] (WAC)").

apply to RICO claims, thereby denying RICO standing to indirect victims." *Id.*; *see also, e.g.*, *Hale v. Stryker Orthopaedics*, 2009 WL 321579, at *3 (D.N.J. Feb. 9, 2009) ("The Third Circuit has extended application of the 'direct purchaser' standing rule to RICO claims.").

The bright-line indirect purchaser rule is an insurmountable obstacle to plaintiffs' RICO claims. Plaintiffs do not, and cannot, allege that they purchase analog insulin directly from any defendant; instead, their allegations confirm that defendants' products are sold "from manufacturer to wholesaler, wholesaler to retailer (or mail order), and retailer to patient." FAC ¶ 167; *see also id.* ¶¶ 163-164, 168, 173. Accordingly, the indirect purchaser rule requires dismissal of plaintiffs' RICO claims, "even if the majority of the injury is borne by [consumers]." *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 94 (3d Cir. 2011); *see also McCarthy*, 80 F.3d at 849 (indirect purchaser rule applies even if "the full cost of the product (and hence one hundred percent of any overcharge) had been passed on"); *Link v. Mercedes-Benz of N. Am., Inc.*, 788 F.2d 918, 930 (3d Cir. 1986) (indirect purchaser rule applies even if inflated prices are "passed on" and "direct purchasers" lack incentive to sue).

Hale v. Stryker Orthopaedics is directly on point. There, the plaintiffs alleged that manufacturers of artificial hip and knee implants violated RICO through a "collusive kickback scheme" that "allegedly inflated the prices charged"

for patients' implants. 2009 WL 321579, at *1. Judge Martini dismissed the RICO claim because the plaintiffs did "not plead that they purchased the joints used in their knee replacement surgeries directly from [the defendants]." *Id.* at *3. The Court explained that "[b]etween [p]laintiffs and [d]efendants in the chain of distribution stand several actors, including the hospitals performing the joint surgeries and plaintiffs' insurers." *Id.* at *4. Accordingly, "[p]laintiffs' co-payment alone does not allow them to stand in the shoes of a direct purchaser for standing purposes." *Id.*

The same is true here. Any putative injury to plaintiffs necessarily first passed through the intermediary entities in the distribution chain. Accordingly, plaintiffs lack standing to assert their RICO claims against defendants. *See Warren*, 643 F.3d at 91, 95 (downstream purchaser of drugs lacks standing to sue manufacturer under antitrust laws); *see also Delaware Valley Surgical Supply Inc. v. Johnson & Johnson*, 523 F.3d 1116, 1122 (9th Cir. 2008) (downstream purchaser of medical products lacked standing under the "sensible and straightforward" and "bright line rule" set forth in *Illinois Brick*); *In re Brand Name Prescription Drugs Antitrust Litig.*, 248 F.3d 668, 670 (7th Cir. 2001) (consumers who "had not purchased . . . drugs directly from the defendants" would lack standing to assert federal antitrust claims).

B. Plaintiffs Do Not Plead Facts Amounting to Mail or Wire Fraud

Plaintiffs fail to plead the existence of any "fraudulent misrepresentation or omission reasonably calculated to deceive persons of ordinary prudence and comprehension," *Lum*, 361 F.3d at 223 (internal citation omitted), much less with the particularity required by Rule 9(b), *see Cephalon*, 620 F. App'x at 85-86. Absent "a specific fraudulent statement," identified by "the time, place, speaker and [its] content," a civil RICO claim grounded in fraud should be dismissed. *Jaye v. Oak Knoll Vill. Condo. Owners Ass'n, Inc.*, 2016 WL 7013468, at *15 (D.N.J. Nov. 30, 2016).

Plaintiffs accuse defendants of having made "false or misleading statements or material omissions regarding the net prices of their analog insulins [and] . . . the existence and amount of their analog insulins' benchmark-to-net price spread." FAC ¶ 349; *see also id.* ¶¶ 2, 254, 303. These allegations are based on two theories, not specific facts. First, plaintiffs allege that the benchmark price defendants charge to wholesalers is "fraudulent" because it is not "a reasonable approximation of the actual price of insulin." *Id.* ¶ 303; *see also id.* ¶¶ 12, 13, 254, 350. Second, plaintiffs allege that defendants engaged in fraudulent omissions by failing to disclose to the public "the substantial rebates from Defendant Drug Manufacturers to PBMs" and "the magnitude of the spreads between benchmark prices and net prices." *Id.* ¶¶ 301-303; *see also id.* ¶¶ 340, 361, 381. As shown

below, neither of these allegations is sufficient to state a plausible predicate act of mail or wire fraud.

1. <u>The Complaint Fails to Allege a Misrepresentation</u>

Plaintiffs' RICO claims fail to allege a misrepresentation by defendants with the specificity required by Rule 9(b) or otherwise. Plaintiffs assert that defendants have increased the "spread" between their benchmark prices and "the true prices of their analog insulins." *Id.* ¶¶ 2-3. But allegedly excessive pricing is not fraudulent. *See, e.g.*, *Eike v. Allergan*, 850 F.3d 315, 318 (7th Cir. 2017) (en banc) ("The fact that a seller does not sell the product that you want, or at the price you'd like to pay, is not an actionable injury."). Even charging different prices to different parties that occupy the same position in the chain of payment is not unlawful. *See Langford v. Rite Aid of Alabama, Inc.*, 231 F.3d 1308, 1313-14 (11th Cir. 2000) (dismissing RICO claim based on allegations that pharmacy "charged plaintiffs more for their prescription medication than it charged other consumers" because "variable pricing is the norm in many industries"); *Bonilla v. Volvo Car Corp.*, 150 F.3d 62, 71 (1st Cir. 1998) ("price disparity is not itself fraud" because "nothing in the law of fraud [] prevents even a single seller from charging different markups").

No doubt aware of this fundamental problem with their claims, plaintiffs try to manufacture an argument that defendants misrepresented "to the general public

and consumers" that their "benchmark prices" are an approximation of the so-called "actual cost of [analog insulins]." *See* FAC ¶ 302. As shown below, however, plaintiffs offer no factual allegations to support that contention.

First, plaintiffs fail to identify—anywhere in their 204-page complaint—a single instance in which defendants represented that their benchmark prices reflect the "actual cost" or "net price" of insulin. To the contrary, the specific statements in the complaint attributed to defendants expressly represent that there is a *difference* between defendants' benchmark price and the net price that defendants receive after the payment of PBM rebates. *See, e.g.*, FAC ¶ 242 (quoting Novo Nordisk statement that focusing on increases in its list prices is "misleading" because the "net price" Novo Nordisk realizes after "rebates, fees and other price concessions we provide to the payer . . . more closely reflects our actual profits"); *id.* ¶ 244 (quoting Sanofi statement explaining that the company had "increased the level of rebates granted for Lantus® in order to maintain favorable formulary positions with key payers"). These express allegations undermine any conclusory assertion that defendants misrepresented the "true" nature of benchmark prices.

Second, having failed to identify any actual misstatements, plaintiffs are left arguing that defendants' "benchmark" prices are themselves fraudulent misrepresentations. FAC ¶¶ 252, 323, 325. Plaintiffs' position appears to be that the "benchmark" prices, as allegedly published by defendants, were understood by

consumers to constitute a "reasonable approximation of the true market prices of their analog insulins" after accounting for PBM rebates. *Id.* ¶¶ 350, 411; *see also id.* ¶¶ 302, 303. Plaintiffs do not offer a single factual allegation that would support that claim. Indeed, any such understanding would be *directly contrary to federal law*, which defines WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price*." 42 U.S.C. § 1395w-3a(c)(6)(B) (2012) (emphasis added).

Moreover, plaintiffs' assertion that WAC was understood to mean the manufacturer's "net price" would defy common sense. WAC relates to prices paid by *wholesalers* and *pharmacies* that purchase and re-sell prescription drugs as part of the physical distribution chain. *See id.*; *see also supra* at 8-9. By contrast, net prices are what manufacturers realize after separately and subsequently paying any rebates to PBMs—payers who are responsible for creating and managing drug formularies.[17]

[17] Likewise, plaintiffs do not allege any facts suggesting that AWP was defined or understood to be a price net of rebates to PBMs. Plaintiffs' counsel themselves have been aware for years that AWP and WAC relate to prices paid by wholesalers and pharmacies, and are not intended to reflect any PBM rebates. Indeed, they have brought numerous cases over the past fifteen years alleging that AWP should reflect the price paid by *pharmacies*, not PBMs. *See, e.g.*, *New England Carpenters Health Benefits Fund v. First Databank, Inc.*, 244 F.R.D. 79,
(….continued)

The Third Circuit has dismissed analogous allegations of fraud. *See Lum*, 361 F.3d at 223. In *Lum*, the plaintiffs argued that the term "'prime rate' [was] so generally understood to mean the lowest rate available to a bank's most creditworthy borrowers that the failure to disclose that some borrowers obtain loans with interest rates below the prime rate constitutes fraud." *Id.* at 226. The court rejected the argument, finding that "the term 'prime rate' is sufficiently indefinite that it is reasonable for the parties to have different understandings of its meaning," and holding that the plaintiffs' RICO claim boiled down to a "disagreement about the meaning" of that term, but that such a disagreement "does not rise to the level of fraud." *Id.* Even more clearly here, plaintiffs' arguments about what "benchmark" prices supposedly represent do not support their accusation of criminal fraud.

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82 (D. Mass. 2007) (in case brought by Hagens Berman, stating that "[h]istorically, drug manufacturers reported the AWP to the publisher at a markup of 20% or 25% from the Wholesale Acquisition Cost ('WAC') for branded single-source, self-administered drugs" and that "[m]anufacturers typically sell drugs to wholesalers on the basis of 'WAC'"); *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 65-66, 68 (D. Mass. 2005) (in case brought by Hagens Berman in 2003, denying class certification for consumers and health insurers who asserted RICO and state consumer protection claims for the private purchase of certain drugs based on allegations that pharmaceutical companies misstated AWPs, and explaining that "WAC is understood to be the price at which a pharmaceutical firm typically sells a drug to wholesalers" and that "[t]ypically, the AWP for a brand-name, self-administered drug is 20% or 25% above WAC").

2. **The Complaint Fails to Allege Any <u>Omission in Violation of a Duty to Disclose</u>**

Plaintiffs' allegations of fraudulent omissions fare no better. Mail or wire fraud can be premised on non-disclosure only when the defendant has a duty to disclose. *See, e.g.*, *United States v. Ciavarella*, 716 F.3d 705, 728-29 (3d Cir. 2013). Here, plaintiffs criticize defendants for "conceal[ing] . . . the substantial rebates from Defendant Drug Manufacturers to PBMs." FAC ¶ 301. Plaintiffs also allege that defendants "conceal . . . the reality that the net prices offered to PBMs in exchange for preferred formulary positions are *exponentially lower*" than published benchmark prices. *Id.* ¶ 302. But defendants were under no legal obligation to disclose either the rebates they pay to PBMs or the net prices they realize after paying any such rebates.

It is a "settled premise that a seller generally has no duty to disclose internal pricing policies or its method for valuing what it sells." *Eller v. EquiTrust Life Ins. Co.*, 778 F.3d 1089, 1092-93 (9th Cir. 2015) (collecting cases); *see also, e.g.*, *Langford*, 231 F.3d at 1313 ("As a general matter of federal law, retailers are under no obligation to disclose their pricing structure to consumers."). In *Langford*, the plaintiffs asserted a civil RICO claim against a pharmacy, alleging that the pharmacy had implemented a scheme to defraud uninsured customers by charging them higher prices than insured customers. The court affirmed the dismissal of the RICO claim, reasoning that "plaintiffs have not alleged any facts that would

suggest that Rite Aid was subject to a duty to disclose the fact that it charged plaintiffs more for their prescription medication than it charged other consumers." *Id.* at 1314. Likewise, here, defendants had no duty to disclose the amount of rebates paid to the PBMs.[18] *See Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 18 (2010) (Ginsburg, J., concurring) (explaining that where defendant "would have owed no duty to disclose [its] sales to anyone," its "failure to disclose could not conceivably be deemed fraud of any kind" (citation omitted)).[19]

3. Plaintiffs Cannot Make Up for Their Failure to Allege Fraud by Labeling Rebates "Kickbacks"

Plaintiffs also contend that defendants' payment of rebates is "unfair, deceptive, and unlawful because it violates the Federal Anti-Kickback statutes." FAC ¶ 331. Even if plaintiffs could demonstrate that paying a rebate amounts to a

[18] Because they cannot allege that the supposedly omitted information would have made a difference, plaintiffs are essentially advancing a "fraud on the market" theory, under which they would have the Court simply presume that defendants' alleged failure to disclose the rebates distorted the price of the drugs at issue. *See In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at *21 (D.N.J. July 10, 2009) (explaining that, where plaintiffs claimed that undisclosed facts led to the artificial inflation of drug prices, this "is actually a classic fraud-on-the-market theory normally pled in securities fraud cases"). This theory "is not cognizable under RICO." *Id.* at *20-21; *see also, e.g.*, *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 2008 WL 5413105, at *9 n.12 (D.N.J. Dec. 23, 2008) (collecting cases demonstrating that the fraud-on-the-market "theory is not recognized in the RICO context, and thus, not a viable theory here").

[19] The FTC opposes disclosure of manufacturer rebates to PBMs because it "may lead to higher prices for PBM services and pharmaceuticals." *See* Creighton, *supra* at p. 18 n.14.

kickback—which they cannot—violations of the Anti-Kickback Statute ("AKS") are not included among the dozens of expressly enumerated RICO predicate acts. *See* 18 U.S.C. § 1961(1). RICO's list of predicate acts "is exhaustive. To read it otherwise would be to usurp the role of Congress in drafting statutes." *Annulli v. Panikkar*, 200 F.3d 189, 200 (3d Cir. 1999) (internal citation omitted), *overruled on other grounds by Rotella v. Wood*, 528 U.S. 549 (2000); *see also Beck v. Prupis*, 529 U.S. 494, 497 n.2 (2000) ("Section 1961(1) contains an exhaustive list of acts of 'racketeering,' commonly referred to as 'predicate acts.'").

Plaintiffs try to avoid this threshold problem by asserting that defendants' alleged violations of the AKS constitute RICO predicate acts of mail and wire fraud. FAC ¶ 331. But courts in this Circuit routinely reject attempts to shoehorn non-RICO predicate acts into a mail or wire fraud claim. *See, e.g.*, *Kolar*, 361 F. App'x at 364 n.10 (rejecting argument that "alleged breach of fiduciary duties" should be considered "predicate mail and wire fraud offenses" under RICO); *Damiano v. Sony Music Enter., Inc.*, 975 F. Supp. 623, 632 (D.N.J. 1996) ("Plaintiff's RICO claims must fail because they are actually nothing more than copyright infringement claims presented as mail fraud and copyright infringement is not a predicate act under RICO."); *Wilkinson Co. v. Krups N. Am., Inc.*, 1999 WL 33134349, at *4 n.9 (D.N.J. Nov. 16, 1999) ("[L]itigants have often attempted to shoehorn 'garden variety' fraud or breach of contract claims into a RICO

claim."). Plaintiffs cannot bootstrap into RICO a predicate act that Congress chose not to include.

In any event, plaintiffs' attempt at transforming every PBM rebate into a "kickback" also misses the mark, because rebates are expressly excluded from the Anti-Kickback Statute. The statute's "corresponding regulations establish a number of 'safe harbors' for common business arrangements," including "rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,734, 23,736 (May 5, 2003). One of the safe harbors protects payments to group purchasing organizations, which include PBMs. 42 C.F.R. § 1001.952(j); *see also* 68 Fed. Reg. at 23,736 (noting that this safe harbor may offer protection for PBM rebates). And a second one covers "discounts," which expressly includes "a rebate . . . the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." 42 C.F.R. § 1001.952(h)(4).[20] In light of these safe harbors, plaintiffs have

[20] Plaintiffs contend that the "discounts" safe harbor does not apply because PBM rebates "are accompanied by the quid pro quo of getting preferred formulary treatment" and "do not reduce the manufacturer's net selling price." FAC ¶ 333. These supposed limitations find no support in the relevant regulation, which does not prohibit a manufacturer from receiving *any* reciprocal benefit in return for a
(….continued)

not plausibly alleged that any rebates paid by defendants to PBMs—which plaintiffs admit is a common, well-known, and established practice across the pharmaceutical industry (FAC ¶¶ 4, 169-170)—amount to unlawful kickbacks.

4. Plaintiffs Cannot Salvage Their Claims Through Unrelated Pharmaceutical Pricing Cases

In an attempt to shore up their allegations of fraud, plaintiffs rely on unrelated pharmaceutical pricing cases, including cases brought by their own counsel in other districts. But the decisions that they cite do not help them, as most involved allegations that the defendants reported an artificially inflated benchmark price that *drug manufacturers did not actually charge*, so that doctors and pharmacies could receive higher reimbursements from Medicare and commercial health plans. Here, by contrast, plaintiffs admit that the "benchmark price" set by defendants is the *actual price* that defendants charge to wholesalers. Plaintiffs' objection is that these benchmark prices are too high because they do not account for the rebates paid to PBMs. But that objection finds no support in the cases that plaintiffs invoke.

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discount or require that a discount reduce the manufacturer's price "net" of the discount over time.

Plaintiffs' reference to *In re Lupron Marketing & Sales Practices Litigation*, 295 F. Supp. 2d 148 (D. Mass. 2003) is inapposite. *See* FAC ¶ 14. There, the defendant manufacturers had pleaded guilty to criminal charges (and paid nearly $900 million in penalties) after admitting that the price that they claimed doctors were paying for their drugs (i.e., the reported AWP) bore no resemblance to the price that the defendants were actually charging doctors. 295 F. Supp. 2d at 159. Instead, the manufacturers were selling to doctors at far lower prices, and even giving their drug away for free. *Id.* at 160-61. The "spread" was between the price reported by the defendants and the actual price that the defendants charged. *Lupron* was thus "a case of affirmative misrepresentation": the reporting of a false artificially inflated price that the defendants did not actually charge. *Id.* at 168. Here, by contrast, plaintiffs allege that the "benchmark price" is an actual price that defendants charge to wholesalers. There is no falsely reported price.

New England Carpenters Health Benefits Fund v. First DataBank, Inc., 244 F.R.D. 79 (D. Mass. 2007) is also inapposite. *See* FAC ¶ 206. It likewise had nothing to do with PBM rebates or any "spread" between benchmark price and the "net price" realized by manufacturers after paying PBM rebates—indeed, it did not even involve any drug manufacturer. Instead, *First DataBank* centered on a "secret agreement" between a wholesaler and a pricing publisher—the existence of which was concealed from others—to fraudulently inflate hundreds of AWPs,

which would increase the profits of pharmacies (the wholesaler's clients). *See New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 248 F.R.D. 363, 367 (D. Mass. 2008). That was contrary to the publisher's representations that it "conduct[ed] surveys of the market to obtain AWP information." *Id.* at 367. Plaintiffs allege no such conduct here.[21]

Finally, plaintiffs egregiously mischaracterize *United States ex rel. Banigan v. Organon USA Inc.*, 2016 WL 6571269, at *1 (D. Mass. Jan. 20, 2016) by citing the court's summary of the plaintiff's allegations as if it were the court's own reasoning. *See* FAC ¶ 209.

C. <u>Plaintiffs Fail to Plead a Valid RICO Enterprise</u>

Plaintiffs attempt to plead six separate bilateral enterprises, each consisting of one manufacturer and one PBM. But plaintiffs fail to plausibly allege either that the enterprise members shared a "common purpose," or that defendants operated or

[21] Plaintiffs highlight that one PBM, Express Scripts, realized that the AWP increases were driving up consumers' prices, and yet considered not flagging this fact so as to protect its own profits. Yet plaintiffs' own allegations show that Express Scripts informed its clients of the AWP increases. FAC ¶ 208 (expressly referring to the "letter" that Express Scripts sent to its clients to inform them); *see First Data Bank*, 248 F.R.D. at 368 & n.6 (noting a factual dispute over how many Express Scripts clients received the letter, but no dispute that it was sent). But that obviously has nothing to do with either manufacturer defendant's conduct in this case (and plaintiffs have specifically opted *not* to sue any PBMs here).

managed the supposed enterprises' affairs (as opposed to each defendant's own affairs).

1. The Complaint Fails to Plausibly Allege that the Members of Each Enterprise Had a "Common Purpose"

An essential element of an association-in-fact enterprise is that its members share a "common purpose." *Boyle v. United States*, 556 U.S. 938, 948 (2009). Plaintiffs allege two "common purposes," both of which are undermined by plaintiffs' own allegations.

First, plaintiffs assert that the members of each alleged enterprise share the "purposes of selling, purchasing, and administering the analog insulins to individual plaintiffs and class members and deriving secret profits from these activities." FAC ¶ 301. But that conclusory assertion is falsified by plaintiffs' own allegations, which show that each member of the alleged enterprise does not share the putative "common purpose" attributed by plaintiffs to the enterprise. Defendants—not PBMs—*sell* analog insulin.[22] *Id.* ¶¶ 400, 412. PBMs—not manufacturers—are involved in *purchasing* analog insulins by contributing to the purchase price. *Id.* ¶ 166. And neither manufacturers nor PBMs *administer* analog insulin; people with diabetes or their caregivers do that. *Id.* ¶¶ 215, 243 n.30. It is

[22] In an exception, PBMs' mail-order pharmacies sell analog insulin directly to consumers. *Id.* ¶¶ 11, 167, 318. By contrast, manufacturers do not sell to consumers. *Id.* ¶¶ 163-164, 167, 170 fig. 3.

the purpose of every business to pursue its own profits, and each defendant and PBM publicly discloses its respective profits but, consistent with general business practices, do not disclose profit margins on particular products.

To the extent that plaintiffs' "common purpose" allegations are predicated on allegations involving "rebate deals" between manufacturers and PBMs (*see, e.g.*, FAC ¶ 306), plaintiffs merely allege conduct that is "consistent with ordinary business conduct and an ordinary business purpose." *In re Jamster Mktg. Litig.*, 2009 WL 1456632, at *5 (S.D. Cal. May 22, 2009).[23] "[C]ourts have overwhelmingly rejected attempts to characterize routine commercial relationships" like these "as RICO enterprises." *Shaw v. Nissan N. Am., Inc.*, 220 F. Supp. 3d 1046, 1054 (C.D. Cal. 2016) (citation omitted); *see also Bible v. United Student Aid Funds, Inc.*, 799 F.3d 633, 655-56 (7th Cir. 2015) (explaining that a "run-of-the-mill commercial relationship where each entity acts in its individual capacity to pursue its individual self-interest" is not a RICO enterprise). That is because "creative wordplay" could always be used to restate a "commercial relationship . . . as a purpose" and hence a RICO enterprise. *Gomez v. Guthy-Renker, LLC*, 2015 WL 4270042, at *5-6 (C.D. Cal. July 13, 2015); *see also*

[23] Indeed, plaintiffs acknowledge that it is standard practice for manufacturers to negotiate with PBMs to ensure patients' access to the manufacturers' drugs. FAC ¶¶ 4, 166, 169.

Crichton v. Golden Rule Ins. Co., 576 F.3d 392, 400 (7th Cir. 2009) (dismissing RICO claim because "garden-variety" business relationships are "not what RICO penalizes"); *Arthur v. Guerdon Indus., Inc.*, 827 F. Supp. 273, 279 (D. Del. 1993) (rejecting enterprise allegations based on mobile home manufacturer's rebates to retailers, and noting that "[t]he state of the business world often requires a manufacturer . . . to provide incentives to a retailer or buyer in order to . . . be successful in the marketplace").

Indeed, plaintiffs' argument that each enterprise shares a "common purpose" of seeking "secret profits" by granting preferential treatment to each defendant's products—"to the exclusion of competitor products" (FAC ¶¶ 310-311)—is self-contradictory. For instance, if CVS Health and Novo Nordisk formed an enterprise to increase market share for Novo Nordisk's insulin products, CVS Health could not also be part of an enterprise with Sanofi to increase the market share for its *competing* insulin products—the enterprises would have directly opposing interests and could not simultaneously share the alleged exclusionary purpose. Plaintiffs effectively admit as much; they allege not that each PBM always gave preferred formulary placement to a single manufacturer, but instead that "the PBMs promise preferred formulary placement to the winning bidder, i.e., *the manufacturer with the highest spread*." *Id.* ¶ 2 (emphasis added). The Court should not credit such internally contradictory allegations. *See, e.g.*, *Lind v. New Hope Prop., LLC*, 2010

WL 1493003, at *6 (D.N.J. Apr. 13, 2010) (dismissing conspiracy claim where conclusory assertions were contradicted by factual allegations); *Payne v. DeLuca*, 433 F. Supp. 2d 547, 612 (W.D. Pa. 2006) (holding that "self-contradictory" allegations were "fatal" to plaintiffs' claims).

Second, plaintiffs allege that each enterprise "shares a common purpose of perpetuating use of insulin benchmark prices as the basis for consumer cost-sharing and out-of-pocket payments." FAC ¶ 304. But as plaintiffs recognize, defendants have no role in insurers' setting of cost-sharing terms for their patients or pharmacies' setting of prices for uninsured patients. *Id.* ¶¶ 165, 169, 175. And plaintiffs have not plausibly alleged that defendants have any preference regarding how those terms are set, much less that defendants have the purpose of "perpetuating" any particular manner of setting those terms.

In any event, plaintiffs' allegations show that what they term the "perpetuati[on]" of benchmark prices is nothing more than defendants' practice of setting a WAC price for sales to wholesalers, defendants' reporting that price to publishers, and the PBMs' negotiation of the price that their affiliated insurers will pay for a drug. *See id.* ¶ 176 ("Prices to wholesalers tend to be based on the benchmark prices that are set by manufacturers or wholesale acquisition costs ('WACs')."); *id.* ¶ 171 ("[T]he patient's payment is based on the medication's *benchmark* price, whereas her insurer's payment is ultimately based on the *net*

price its PBM negotiated."). Defendants and PBMs do not perpetuate anything by participating in the ordinary means of setting prices for brand drugs. And plaintiffs themselves explain that use of "benchmark prices" in the pharmaceutical industry has multiple benefits: "The use of price benchmarks to calculate and communicate reimbursement payments reflects an efficient method by which to maintain the system's flexibility, minimize uncertainty through predictable costs, maximize coverage in a cost-effective manner, and provide a mechanism for competition among payers." *Id.* ¶ 177. Given these advantages, it is implausible to allege that the use of benchmark prices for a handful of analog insulins could have the purpose of "perpetuating" the use of benchmark prices.[24]

[24] Moreover, this ordinary commercial approach to pricing will remain in use regardless of any efforts taken or not taken by defendants or PBMs. As noted above, Congress defines the WAC benchmark and requires its use in setting payment rates for Medicare and Medicaid beneficiaries. *See supra* p. 8; 42 U.S.C. § 1395w-3a(c)(6)(B). And publishers will continue reporting the prices that the manufacturers charge wholesalers, no matter what defendants or PBMs do. As plaintiffs' counsel knows well from past cases they have brought, an assortment of "[p]rivate publications such as the Drug Topics Red Book, the First Data Bank Blue Book, and the Medi-Span Master Drug Data Base list the AWPs" and the "[r]elated" WAC. *In re Pharm. Indus. Average Wholesale Price Litig*., 230 F.R.D. 61, 67-68 (D. Mass. 2005) (case brought by Hagens Berman, among others). It is nonsensical to say that the alleged RICO enterprises had a purpose of perpetuating a thoroughly entrenched—and legally mandated—practice.

2. The Complaint Fails to Plausibly Allege that Defendants Conducted the Alleged Enterprises' Affairs

Plaintiffs are required to plausibly plead that "defendants conducted or participated in the conduct of the '*enterprise's* affairs,' not just their *own* affairs." *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993). Where those allegations "are entirely consistent with . . . each [enterprise member] going about its own business" within "the bounds of the parties' normal commercial relationships," this requirement is unsatisfied. *United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 855-56 (7th Cir. 2013).

Plaintiffs cannot show that defendants participated in the conduct of a RICO enterprise by engaging in arm's-length negotiations with PBMs. This is simply the negotiating framework inherent in *any* manufacturer-PBM relationship. Plaintiffs' allegations are similar to those rejected in *Walgreen*. There, the plaintiff alleged that a pharmacy chain (Walgreens) and drug manufacturer (Par Pharmaceutical) worked together to defraud insurers by filling prescriptions for generic drugs with a dosage form that was more expensive than the dosage form prescribed by the physician. *Id.* at 850-53. Although the plaintiff alleged "various communications" through which Par encouraged Walgreens to engage in this practice and Walgreens "agreed to implement it," the Seventh Circuit held that these interactions "show[] only that the defendants had a commercial relationship, not that they had joined

together to create a distinct entity for purposes of improperly filling . . . prescriptions." *Id.* at 854-55. Because "[t]he allegations in the complaint do not indicate how the cooperation in this case exceeded that inherent in every commercial transaction between a drug manufacturer and pharmacy," the court could "[]not find a basis for inferring that Walgreens and Par were conducting the enterprise's affairs." *Id.* at 856.

Similarly here, plaintiffs' allegations are "entirely consistent with [defendants and the PBMs] each going about [their] own business." *Id.* at 855. Manufacturers set benchmark prices and pay rebates to PBMs; PBMs determine formulary placement. Neither defendant "can be said to have controlled and conducted [an] enterprise rather than merely its own affairs" by engaging in this routine, well-known, and governmentally accepted conduct. *Crichton*, 576 F.3d at 399; *see also Moss v. BMO Harris Bank, N.A.*, 258 F. Supp. 3d 289, 304 (E.D.N.Y. 2017) (concluding that, even if plaintiffs "adequately pled the defendants had 'worked together in some respects to steal the plaintiffs' funds,' there were no plausible allegations 'that they did so to advance the agenda of their purported 'enterprise' or for any shared purpose'" (citation omitted)).

D. Plaintiffs Do Not Adequately Plead Proximate Causation

To state a RICO claim, a plaintiff "must satisfy RICO's proximate causation requirements." *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d

633, 638 (3d Cir. 2015). Proximate causation requires a "direct relation" between the injury asserted and the alleged predicate acts. *Hemi*, 559 U.S. at 9. Proximate causation is absent if the plaintiff's alleged injuries "could have resulted from factors other than [the defendants'] alleged acts of fraud." *Anza v. Ideal Steel Supply Corp*., 547 U.S. 451, 459 (2006).

Because defendants' alleged failure to disclose the so-called "real" price of analog insulin had no effect—let alone a direct effect—on the price that plaintiffs paid, plaintiffs have failed to adequately allege proximate cause. Plaintiffs assert that "[b]ut for the misrepresentations that the Defendant Drug Manufacturers made regarding the benchmark prices of their analog insulins and the scheme that the Manufacturer-PBM Insulin Pricing Enterprises employed, plaintiffs and others similarly situated would have paid less, out-of-pocket, for their analog insulins." FAC ¶ 341. But even if defendants disclosed the net price they realized after accounting for PBM rebates, there is no basis for concluding that the prices consumers pay at the pharmacy counter—which, as noted above, are set by insurers and pharmacies, and not by defendants—would have been any different.[25]

[25] Moreover, to the extent that plaintiffs are dissatisfied with their own insurers' failure to apply any manufacturer rebates to reduce the prices that consumers pay at the point of sale, PBMs' alleged misleading of consumers by "us[ing] the defendants' benchmark prices as a basis for consumer cost-sharing"
(….continued)

In explicitly framing their theory in terms of "but for" causation (FAC ¶ 341), plaintiffs effectively concede that they cannot show the direct relationship required to establish proximate causation. *See Hemi*, 559 U.S. at 9 (explaining that a plaintiff "is required to show that a RICO predicate offense 'not only was a "but for" cause of his injury, but was the proximate cause as well'" (citation omitted)).

Courts reject RICO claims where alleged misrepresentations did not cause the plaintiffs' alleged injuries. As one district court has explained, a plaintiff cannot prove proximate causation where "the rebates that were not disclosed had no effect on the decisions of the plaintiffs to incur [costs]." *Arthur*, 827 F. Supp. at 280. Likewise, here, defendants' supposed misrepresentations or omissions about rebates have no connection to the prices plaintiffs ultimately paid for insulin. Knowing the details of the rebates would not have entitled consumers to any corresponding discount, nor would it have in any other way altered the prices pharmacies charge at the counter—which, again, are not set by defendants. *See also Dow Chem. Co. v. Exxon Corp.*, 30 F. Supp. 2d 673, 695-96 (D. Del. 1998)

(continued….)

(*id.* ¶ 13), or pharmacies' unilateral pricing decisions, their injury has "resulted from factors other than [defendants'] alleged acts of fraud." *Anza*, 547 U.S. at 459.

(dismissing RICO claim where the plaintiff's "losses do not stem directly from [the] alleged misrepresentations").[26]

E. Plaintiffs Do Not Adequately Plead a RICO Conspiracy

Plaintiffs also allege that defendants violated section 1962(d) by "agreeing and conspiring" with one another "to violate 18 U.S.C. § 1962(c)." FAC ¶ 348. As an initial matter, this RICO-conspiracy claim fails because plaintiffs' substantive RICO claim under section 1962(c) fails for the reasons set forth above. It is well established that "a § 1962(d) claim must be dismissed if the complaint does not adequately allege 'an endeavor which, if completed, would satisfy all of the elements of a substantive [RICO] offense.'" *In re Ins. Brokerage*, 618 F.3d at 373 (quoting *Salinas v. United States*, 522 U.S. 52, 65 (1997)); *see also, e.g.*, *Paramount Enter., Inc. v. Laborers E. Region Org. Fund.*, 2014 WL 791825, at *4

[26] This case thus presents the opposite of the situation in *Avandia*. There, the Third Circuit found RICO's proximate-causation requirement satisfied where the defendant manufacturer allegedly had misrepresented the safety of an insulin drug (Avandia) *directly* to the plaintiff third-party payors, which relied on the misrepresentation in deciding to "include[] Avandia in their formularies and cover[] Avandia at favorable rates in reliance on these misrepresentations." 804 F.3d at 636. The court held that "[t]he conduct that allegedly caused plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia that caused [plaintiffs] and PBMs to place Avandia in the formulary." *Id.* at 644. Unlike in *Avandia*, plaintiffs do not (and cannot) allege that defendants' alleged nondisclosure of rebates directly impacted their purchasing decisions.

(D.N.J. Feb. 25, 2014) ("Because the Court finds that Plaintiffs' § 1962(c) claim is deficient, it follows that Plaintiffs' conspiracy claim must be dismissed.").

Plaintiffs' conspiracy claim also fails on its own merits. To be liable for conspiracy under § 1962(d), a defendant must "knowingly agree[] to facilitate a scheme which includes the operation or management of a RICO enterprise." *The Knit With v. Knitting Fever, Inc.*, 625 F. App'x 27, 35 (3d Cir. 2015) (citations omitted). Plaintiffs therefore must plausibly "allege facts suggesting that [defendants] knowingly agreed to facilitate an[] illegal scheme." *Mason v. Campbell*, 2016 WL 8716458, at *6 (E.D. Pa. July 29, 2016) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When a plaintiff attempts to allege a conspiracy, "evidence of parallel conduct by alleged co-conspirators is not sufficient to show an agreement"; instead, the allegations "'must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action.'" *In re Ins. Brokerage*, 618 F.3d at 321-22 (quoting *Twombly*, 550 U.S. at 557).

Plaintiffs have not set forth any such allegations. In fact, they do not offer *any* allegations of an agreement between Sanofi and Novo Nordisk, and instead acknowledge that defendants are "competitors." FAC ¶ 10; *see also id.* ¶¶ 312-313. Nor can plaintiffs get around this by alleging that defendants have increased their benchmark prices "in perfect lock-step." *Id.* ¶ 239. Parallel price-matching

decisions can be just as consistent with competition as with collusion, and thus are insufficient to support a conspiracy claim in the absence of facts plausibly showing the existence of an agreement between defendants. *See In re Text Messaging Antitrust Litig.*, 782 F.3d 867, 879 (7th Cir. 2015) (reasoning, in a case involving price-matching, that the "circumstantial evidence consistent with an inference of collusion" was "equally consistent with independent parallel behavior"); *Valspar Corp. v. E.I. Du Pont De Nemours*, 152 F. Supp. 3d 234, 248 (D. Del. 2016) (explaining that "parallel rises in price" by competitors "may not be because they've agreed not to compete but because all of them have determined independently that they may be better off with a higher price" (quotations omitted)), *aff'd*, 873 F.3d 185 (3d Cir. 2017). Therefore, in order "to raise an inference of conspiracy" in the Third Circuit, a plaintiff is "required to show that [defendants'] parallel pricing went beyond mere interdependence [and was] so unusual that in the absence of advance agreement, no reasonable firm would have engaged in it." *Valspar*, 873 F.3d at 195.

Plaintiffs allege that defendants' price increases are implemented for the purpose of facilitating increasing rebates paid to PBMs, on whose formularies defendants compete for preferred placement. FAC ¶ 10. These allegations undermine any suggestion of an agreement between defendants, and instead reaffirm that defendants' price increases represent "independent action" (*Twombly*,

550 U.S. at 557) designed to secure favorable placement on the PBMs' formularies. Because plaintiffs have failed to adequately allege any agreement between defendants, their RICO conspiracy claim must be dismissed.

II. The New Jersey Consumer Fraud Act Claims Should Be Dismissed for Failure to State a Claim

A. The Complaint Fails to Plead the "Deceptive Practices" and "Unconscionable Pricing" Claims with Specificity

Plaintiffs' NJCFA claims,[27] like their RICO claims, sound in fraud, and thus should be dismissed because they lack the particularity required by Rule 9(b). *See DeGennaro*, 2017 WL 2693881, at *5 ("The heightened pleading standard set forth in Rule 9(b) applies to plaintiff's [NJCFA] and common law fraud claims.").[28] Plaintiffs offer only unsupported allegations accusing defendants of "misrepresenting" or "concealing" pricing information, and claiming that defendants "knew, but did not disclose" information related to the cost of their insulin products and the rebates paid to PBMs. FAC ¶¶ 362-364, 382-384.

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[27] Plaintiffs bring three claims under the NJCFA: one against Novo Nordisk for deceptive practices (Count Three), one against Sanofi for deceptive practices (Count Four), and one against Sanofi and Novo Nordisk for unconscionable business practices (Count Five).

[28] Plaintiffs' allegations of "unconscionable" pricing practices arise out the same alleged course of conduct as their other NJCFA claims and RICO claims. *See* FAC ¶¶ 397-404. "Because the underpinning of [plaintiffs' NJCFA] claim is fraud," Rule 9(b) applies to their unconscionable practices claim as well. *Gray v. Bayer Corp.*, 2009 WL 1617930, at *2 (D.N.J. June 9, 2009).

Plaintiffs do not identify with specificity how defendants purportedly violated the NJCFA. Indeed, because defendants use their respective WAC prices (consistent with the federal statutory definition) as their basis for sales to wholesalers, plaintiffs are unable to identify when and where any purported misrepresentations about "true prices" were made, or who made any such statements. Thus, the NJCFA claims must be dismissed.

B. The Complaint Does Not Plead Unlawful Conduct by Defendants

Plaintiffs have failed to plead any unlawful conduct by defendants. Plaintiffs' allegations are predicated on alleged "deceptive" and "unconscionable" practices. *See, e.g.*, *id.* ¶¶ 364, 384, 404. The "capacity to mislead is the prime ingredient of deception or an unconscionable commercial practice." *Sickles v. Cabot Corp.*, 877 A.2d 267, 276 (N.J. Super. Ct. App. Div. 2005). As shown above, plaintiffs have failed to identify any actions by defendants that were capable of misleading consumers as to analog insulin pricing or rebates. *See id.* at 277 (dismissing NJCFA claim where plaintiff "failed to set forth any factual allegations to demonstrate a capacity to mislead").

Moreover, because plaintiffs have not identified a single affirmative misrepresentation or violation of a duty to disclose by either defendant, plaintiffs cannot state a claim for a "deceptive" practice. *See Billings v. Am. Express Co.*, 2011 WL 5599648, at *9 (D.N.J. Nov. 16, 2011) (explaining that "affirmative

misrepresentation[s]" and "knowing omission[s] . . . accompanied by an intent that others rely upon the omission" constitute unlawful conduct). Nor do plaintiffs' references to the Anti-Kickback Statute suffice, because (as explained above) plaintiffs have not plausibly alleged that defendants' commonplace rebates amount to unlawful kickbacks.

Plaintiffs' allegations of "unconscionable" pricing similarly fail. New Jersey courts have uniformly rejected the notion that allegedly "excessive prices" themselves constitute an unconscionable commercial practice. *See, e.g.*, *Quigley v. Esquire Deposition Servs., LLC*, 975 A.2d 1042, 1048 (N.J. Super. Ct. App. Div. 2009) ("Plaintiff has not cited any authority for his argument that a Consumer Fraud Act claim may be stated solely by an allegation that the price of a product was excessive . . . ."); *Yingst v. Novartis AG*, 63 F. Supp. 3d 412, 416 (D.N.J. 2014) (dismissing NJCFA claim where plaintiff's "only contention [was] that [d]efendant engaged in an unconscionable commercial practice by charging a higher price").[29] Conduct that merely causes "consumer dissatisfaction" is not unconscionable. *Billings*, 2011 WL 5599648, at *9.

[29] The cases cited in the complaint do not suggest otherwise. *See* FAC ¶ 397 n.55. In each of these cases, plaintiffs alleged that defendants had engaged in deceptive marketing aimed at vulnerable consumers and failed to deliver the goods or services that were promised, *in addition to* charging an allegedly excessive price. *Kugler v. Romain*, 279 A.2d 640, 651-53 (N.J. 1971) (defendants engaged
(….continued)

C. The Complaint Does Not Allege that Plaintiffs Suffered Any "Ascertainable Loss"

The NJCFA claims also fail because plaintiffs have not established (and cannot establish) the "ascertainable loss" required by the statute. To show "ascertainable loss," a plaintiff must show one of the following: (1) that the "product received was essentially worthless," under the "out-of-pocket theory," or (2) that she was "misled into buying a product that [was] ultimately worth less than the product that was promised," under the "benefit of the bargain theory." *DeGennaro*, 2017 WL 2693881, at *7 (citations omitted). A plaintiff who seeks to demonstrate ascertainable loss under the "benefit of the bargain theory" must allege both a "reasonable belief about the product induced by a misrepresentation" and also that the "difference in value between the product promised and the one

(continued….)

in door-to-door canvassing, selling "educational packages" that were "practically worthless for that purpose" at an "exorbitant price"); *In re Nat'l Credit Mgmt. Grp.*, 21 F. Supp. 2d 424, 452-53 (D.N.J. 1998) (defendant "prey[ed] upon economically disadvantaged individuals" and charged "grossly excessive" fees for credit screening while "provid[ing] services of limited value in return"); *In re Fleet*, 95 B.R. 319, 336 (E.D. Pa. 1989) (defendants marketed financial counseling services that it "could not and did not provide" to "financially troubled and distraught" consumers, then charged consumers an excessive fee "simply for referring them to an attorney"); *Pro v. Hertz Equip. Rental Corp.*, 2012 WL 12906183, at *1 (D.N.J. June 25, 2012) (defendants deceptively collected $151 million in coverage fees for car rentals, but only provided coverage for a small number of loss claims).

received can be reasonably quantified"; a "failure to quantify this difference in value results in the dismissal of a claim." *In re Gerber Probiotic Sales Practices Litig.*, 2014 WL 3446667, at *3 (D.N.J. July 11, 2014) (citation omitted).

The complaint fails to state any claims under the NJCFA because it does not plead ascertainable loss. *See DeGennaro*, 2017 WL 2693881, at *6. It does not state claims under the "out-of-pocket" theory because it contains numerous allegations that show the significant value of insulin to diabetics, which preclude any inference that the medication is "worthless." *See id.* at *7. Indeed, plaintiffs repeatedly emphasize that insulins produced by defendants are "unquestionably the best course of treatment" for Type I diabetics and the "most convenient initial insulin regimen" for Type II diabetics. FAC ¶¶ 231-232 (quotation omitted).

Nor does the complaint state a claim under the "benefit of the bargain" theory. Indeed, plaintiffs make no attempt to allege that they were misled about any of the benefits of insulin, and their conclusory assertions that defendants "inflate" the prices of insulins (*e.g.*, *id.* ¶¶ 10, 211) rest solely on allegations that payments made by certain consumers are based on prices that are (not surprisingly) higher than the prices paid by some insurers and the average net price received by the manufacturer. Instead of alleging that they were misled about the benefits of insulin, plaintiffs allege that defendants made unspecified misleading statements

and omissions regarding "the true costs of . . . analog insulins"—which is, among other problems, incoherent. *See, e.g.*, *id.* ¶ 350.

Plaintiffs do not allege any "reasonable belief about [insulin] induced by a misrepresentation" or that there was any "difference in value between the [insulin] promised and the [insulin] received"—much less that any such difference "can be reasonably quantified." *In re Gerber*, 2014 WL 3446667, at *3. Therefore, plaintiffs have failed to allege an ascertainable loss under the "benefit of the bargain" theory.[30] *See, e.g.*, *Truglio v. Planet Fitness, Inc.*, 2016 WL 4084030, at *8 (D.N.J. July 28, 2016) (holding that plaintiff had failed to "plausibly allege that there is a difference in value between the gym membership [she was] promised . . . and the one received . . . or that such difference can be reasonably quantified"); *see also Franulovic v. Coca Cola Co.*, 2007 WL 3166953, at *8-10 (D.N.J. Oct. 25,

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[30] Some judges in this District have identified in dictum "nominal overcharge" as a third category of ascertainable loss. *See, e.g.*, *Truglio*, 2016 WL 4084030, at *6. However, that treatment of ascertainable loss appears to be a misinterpretation of New Jersey law. Courts discussing "nominal" charges have done so in the context of the type of loss for which class actions are an appropriate mechanism, rather than as a third cognizable type of loss. *See Lee v. Carter-Reed Co.*, 4 A.3d 561, 583 (N.J. 2010) (explaining that a class action was a "superior adjudicative method" for resolving claims due in part to the nominal value of each class member's claim); *Bosland v. Warnock Dodge, Inc.*, 964 A.2d 741, 751 (N.J. 2009) ("When confronted, as we are here, with a plaintiff who asserts that she was the victim of an overcharge which itself is small in amount, and who seeks recovery for herself and on behalf of numerous others with 'nominal' claims, we cannot overlook the reality that, without the remedy that the [NJCFA] affords, all of those wrongs might go unvindicated.").

2007) (explaining that "broad and conclusory allegations are not sufficient to demonstrate an ascertainable loss" under the NJCFA (citation omitted)).

In effect, plaintiffs' NJCFA claims rely on a novel and exceedingly amorphous "price inflation" theory. But New Jersey courts have expressly rejected attempts to rely on such theories in the NJCFA context. *See Dugan v. TGI Fridays, Inc.*, 171 A.3d 620, 640 (N.J. 2017) (noting decisions explaining that permitting plaintiffs to rely on such a theory would "effectively eliminate the ascertainable loss and causation requirements that differentiate consumer CFA claims from Attorney General enforcement actions under the statute"). Thus, courts dismiss NJCFA claims where it is clear that plaintiffs are attempting to rely on a "price inflation" theory in lieu of a concrete showing of ascertainable loss, and plaintiffs' NJCFA claims should be dismissed for that reason as well. *See, e.g.*, *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at *20-21, *31 (D.N.J. July 10, 2009); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178-79 (N.J. Super. Ct. App. Div. 2003).

III. <u>The FAC Should Be Dismissed with Prejudice</u>

Dismissal with prejudice is appropriate where a plaintiff "has already amended its complaint on two separate occasions and has still failed to plead sufficient facts." *DelRio-Mocci v. Connolly Props. Inc.*, 2009 WL 2989537, at *2 (D.N.J. Sept. 16, 2009), *aff'd*, 672 F.3d 241 (3d Cir. 2012); *see also Malobich v.*

Norfolk S. Ry. Co., 2013 WL 1182237, at *4 (W.D. Pa. Mar. 21, 2013) (dismissing amended complaint with prejudice where allowing further attempts to amend would "provide an opportunity for a third bite at the apple"). This is the fourth complaint filed by co-lead counsel Hagens Berman in this case.[31] And accounting for the various complaints filed in the now-consolidated matters, this is plaintiffs' *seventh* attempt. The most recent amendment was made in direct response to the defendants' motion to dismiss, and yet plaintiffs still have been unable to cure the deficiencies identified by defendants.

With respect to some arguments (e.g., that plaintiffs are barred by the indirect-purchaser rule and have not plausibly alleged proximate causation), plaintiffs have not even attempted to repair the flaws in their allegations—which is unsurprising, as there is simply no way for plaintiffs to plead around these problems. With respect to other arguments (e.g., that plaintiffs have failed to allege either any fraudulent representation or omission or valid RICO enterprises),

[31] For a number of the plaintiffs in this case, the FAC represents their third amendment. These plaintiffs include: Donald Chaires, Gerald Girard, Sara Hasselbach, Marilyn Person, and Karyn Wofford. *See* Complaint, *Chaires et al. v. Novo Nordisk Inc. et al.*, Dkt. 1, No. 3:17-cv-00699 (D.N.J. Feb. 2, 2017); Amended Class Action Complaint, *In re Insulin Pricing Litig.*, Dkt. 18, No. 3:17-cv-00699 (Mar. 17, 2017); Consolidated Amended Class Action Complaint, *In re Insulin Pricing Litig.*, Dkt. 82, No. 3:17-cv-00699 (Dec. 26, 2017); First Amended Class Action Complaint, *In re Insulin Pricing Litig.*, Dkt. 141, No. 3:17-cv-00699 (Mar. 29, 2018).

plaintiffs have attempted to paper over the deficiencies in their complaint, but have been unable to do so—which is also unsurprising, as these problems will exist regardless of the rhetoric plaintiffs deploy.

Because it is apparent that "a fourth bite at the apple would be futile" (*Mann v. Brenner*, 375 F. App'x 232, 240 n.9 (3d Cir. 2010)), the FAC should be dismissed in its entirety with prejudice.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the RICO claims and the NJCFA claims in the First Amended Class Action Complaint be dismissed with prejudice.

Dated: May 14, 2018

Respectfully submitted,

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